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510(k) SUMMARY

510(k) NUMBER: PENDING

SUBMITTED BY: Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA-92688
(949) 713-8000

CONTACT PERSON: Anil Bhalani
Director of Regulatory Affairs and Clinical Programs

DATE OF PREPARATION: November 3, 2000

NAME OF DEVICE: Suction Irrigator

CLASSIFICATION NAME: Laparoscope, General & Plastic Surgery.
(Regulation Number 21CFR 876.1500, Endoscope and accessories).

TRADE NAME: Applied SI Suction Irrigator

PREDICATE DEVICE: Trump-It II and Magnum 250, Valley West, Inc, Meridian, Texas. [K973814].

SUMMARY STATEMENT:

The Applied SI Suction Irrigator is indicated for use in patients undergoing general laparoscopic surgical procedures. It is designed to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to evacuate blood, tissue debris, and smoke from the surgical site. The Applied SI Suction Irrigator consists of a handpiece equipped with 2 trumpet style valves, a stainless steel probe, and 2 connecting lines of tubing, one designed to attach to a supply of irrigation fluid, and the other designed to attach to an aspiration pump. The valves allow controlled irrigation and aspiration during a surgical procedure. Low flow aspiration can be achieved without continual manual depression of the suction button by rotating the suction button clockwise until the desired rate of aspiration is achieved.

The handpiece of the suction irrigator is designed to allow instruments to be introduced through the suction irrigation probe to reach the operative site. The instrument adapter is adjustable to allow a variety of instruments, diameter sizes ranging from 2mm to 5mm to pass through without either a loss of pneumoperitoneum or leakage of fluid. A probe is attached to the handpiece, via a quick disconnect coupling. The quick disconnect coupling allows different types and sizes of probes to be attached to the handpiece during surgery.

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The suction irrigator is a single use disposable device and is sold sterile.

The Applied SI Suction Irrigator is substantially equivalent to the Trump-It II and Magnum 250 manufactured by Valley West, Inc., Meridian, Texas. The Applied SI Suction Irrigator is substantially equivalent to predicate devices and introduces no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2001

Mr. Anil Bhalani
Director of Regulatory Affairs and Clinical Programs
Applied Medical
22872 Avenida Empresa
RANCHO SANTA MARGARITA CA 92688

Re: K003443
Applied SI Suction Irrigator
Dated: November 3, 2000
Received: November 6, 2000
Regulatory Class: II
21 CFR §876.4370/Procode: 78 FHF
Unclassified/Procode: 78 LJH

Dear Mr. Bhalani:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Suction Irrigator "Indications for Use" as required.

510(k) Number: ~~Not assigned~~ K003443

Device Name: Suction Irrigator

Indications for Use: The Applied SI Suction Irrigator is indicated for use in patients undergoing general laparoscopic surgical procedures.

Signature: _____ Title: *Director RA/Clinical Programs* Date: *11-3-00*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The -Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David C. Segman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003443